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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,322	07/28/2003	Beppino C. Giovannella	3603-030-03	4446

33432 7590 02/10/2006  
KILYK & BOWERSOX, P.L.L.C.  
400 HOLIDAY COURT  
SUITE 102  
WARRENTON, VA 20186

EXAMINER

WEDDINGTON, KEVIN E

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/628,322

Applicant(s)

GIOVANELLA ET AL.

Examiner

Kevin E. Weddington

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 10 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4, 7 and 9-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 7 and 9-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Claims 1, 4, 7 and 9-19 are presented for examination.

Applicants' amendment filed November 10, 2005 has been received and entered.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 7 and 9-19 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating malignant melanoma with the oral administration of 20(S)-camptothecin or 9-nitro-20(S)-camptothecin at an effective dosage of 1 mg/kg/day, does not reasonably provide enablement for other malignant tumors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention

- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to a method of a malignant tumor in a mammal comprising administering orally to said mammal in need of such treatment an effective amount of a water-insoluble camptothecin compound with a closed-lactone ring at a dose that is an effective amount to inhibit the growth of or retard cancer or kill malignant cells or reduce the volume or size of malignant tumors, wherein said dose is lower than 1.5 mg/Kg/day, wherein said compound is selected from 20(S)-camptothecin and 9-nitro-20(S)-camptothecin.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

The present invention is unpredictable unless experimentation is shown for the instant compounds, 20(S)-camptothecin or 9-nitro-20(S)-camptothecin are effective in treating all types of malignant tumors or cancers

The breadth of the claims

The claims are very broad and inclusive to all types of malignant tumors or cancers orally treated with the administration of compounds disclosed in claim 1.

The amount of direction or guidance provided and the presence or absence of working examples

The Cecil Reference, Textbook of Medicine, 21<sup>st</sup> Edition, 2000, Chapter 198, pages 1060-1074; shows that for the various known cancer types, there is no one specific chemotherapeutic agent that is effective for all types of cancer. (See Table 198-5 at page 1065; Table 198-6 at page 1066; Table 198-8 at page 1068; and Table 198-9 at page 1071).

The working examples set forth in Example 1, Table 1, show the administration of 20(S)-camptothecin and 9-nitro-20(S)-camptothecin, intramuscularly or intravenously at a dose of 4 mg/kg/day.

The working examples set forth in Example 1, Table 2 are limited to the oral administration of 20(S)-camptothecin, 9-nitro-20(S)-camptothecin at a dose of 1 mg/kg/day to treat malignant melanoma only.

No examples showing the oral administration of the instant compounds disclosed in claim 1 to treat other various malignant tumors or cancers as set forth in claims 9-13 and 15-19 at a dose lower than 1.5 mg/kg/day.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to how the treatment of other malignant tumors set forth in claims 9-13 and 15-19 with the said compounds of claim

1 by orally administering at the said dose lower than 1.5 mg/kg/day is undue.

Therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

Claims 1, 4, 7 and 9-19 are not allowed.

The rejection made under 35 USC 112, first paragraph is adhered to.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4, 7 and 9-19 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is again rendered indefinite by the phrase “a dose lower than 1.5 mg/kg/day” which can be interpreted that a dose of 0 mg can be effective in that treatment of a malignant tumor.

The remaining claims 4, 7 and 9-19 are rendered indefinite to the extent that they incorporate the above terminology.

The rejection made under 35 USC 112, second paragraph is adhered to.

Claim 1, 4, 7 and 9-19 are not allowed.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Kevin E. Weddington  
Primary Examiner  
Art Unit 1614

K. Weddington  
February 5, 2006